No. 95-728

In the Supreme Court

OF THE

United States

OCTOBER TERM, 1995

WARNER-JENKINSON COMPANY, INC.,
Petitioner,
v.
HILTON DAVIS CHEMICAL CO.,
Respondent.

On Writ of Certiorari to the United States Court of Appeals for the Federal Circuit

BRIEF OF AMICUS CURIAE CHIRON CORPORATION IN SUPPORT OF RESPONDENT

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STATEMENT OF INTEREST

Founded in 1981 by scientists at the University of California, Chiron Corporation ("Chiron"), with more than seven thousand employees, is the world's largest biotechnology company. Chiron applies biotechnology and other techniques of modern biology to develop products intended to lower the overall cost of healthcare and improve the quality of life by diagnosing, preventing, and treating disease. To carry out this mission, Chiron invests heavily in biological

research. Last year, Chiron spent over $300 million on research and development; in the past five years, Chiron's research and development expenditures averaged nearly 40 percent of its annual revenues. Chiron's inventions include the first genetically engineered vaccine for hepatitis B, the first drug to treat multiple sclerosis, blood tests used worldwide to screen donated blood for HIV (the virus that causes AIDS) and hepatitis C virus, drugs to treat cancer, and a genetically engineered form of the whooping cough vaccine which eliminates the risks to children of the traditional vaccine.

As do other biotechnology companies, Chiron depends on patent protection to achieve adequate returns on its research outlay to encourage stockholder investment. Chiron now owns over two thousand United States and foreign patents. Chiron has also taken a lead role in litigating issues related to biotechnology patent protection, including both infringement actions against companies that seek to use its patented technologies without a license and appeals from Patent and Trademark Office ("PTO") decisions related to issues of patentability for biotechnology inventions. *See, e.g., In re Bell*, 991 F.2d 781 (Fed. Cir. 1993); *Chiron Corp. v. Abbott Labs., Inc.*, 902 F. Supp. 1103 (N.D. Cal. 1995); *cf. In re Deuel*, 51 F.3d 1552 (Fed. Cir. 1995) (appearing on behalf of Amici). From its vantage point on the cutting edge of biotechnology law, Chiron has a unique perspective on the necessity of the doctrine of equivalents to ensure adequate protection for biotechnology inventions.[1]

SUMMARY OF ARGUMENT

The doctrine of equivalents fills a critical role in United States patent law. Since at least 1853, inventors, industries,

[1] Written consent to the filing of this brief has been obtained from Petitioner and Respondent, and is lodged herewith.

and their patent counsel have benefited from the application of the doctrine to "temper the unsparing logic" of literal infringement. By deterring infringement through insubstantial alterations to a patented invention, the doctrine has protected inventors' intellectual property rights and ensured fair returns on their investments in innovation, without creating uncertainty about the scope of patents.

The biotechnology industry and the consumers of the industry's medical innovations benefit from a healthy application of the doctrine of equivalents. Patent protection for biotechnological inventions has attracted investment capital to the industry, making possible the research necessary to discover and develop life-saving and life-improving medical treatments at a time when public funding for research is on the decline. Because of peculiar features of biotechnology inventions, and because of the law that the Federal Circuit has developed to deal with those inventions, the doctrine of equivalents is crucial to protect biotechnology inventions adequately. Without such patents, however, the industry would be unable to attract investment, and could not continue the research necessary to develop new treatments and save lives.

Biotechnology patents also illustrate the need for the doctrine of equivalents to protect patentees' property rights against loss from alterations found to be equivalent after a patent is filed. Biotechnology presents two such problems. First are modifications that have no effect on an invention, such as certain substitutions of one amino acid for another in a large protein molecule. Allowing later-discovered modifications such as these to avoid infringement could obliterate the value of an inventor's patent grant. Second are improvements that build upon an invention, adding additional features or properties. In the case of improvements, the improvement itself may be patentable.

That fact, however, should not limit the rights of the inventor whose basic invention is being exploited.

The loss of the doctrine of equivalents, or a substantial reduction in its scope, would be a serious blow to the biotechnology industry's viability. It would not, however, provide the certainty in claim interpretation that Petitioner seeks. Inherent limits in the ability of language to describe "the heart of an invention" preclude absolute certainty regarding the scope of patent claims, even in cases of literal infringement. Without the doctrine of equivalents, patent attorneys would attempt to protect against insubstantial alterations to an invention by blurring the borders of their claims, making literal infringement determinations even more difficult. Moreover, if patent attorneys could no longer rely on the doctrine of equivalents, the number of claims per patent would rise, as would the complexity of each claim. Parties seeking to determine whether they infringe a patent would be buried in an avalanche of information, and would have *more* difficulty drawing conclusions about infringement than they do today.

As the brief of the Solicitor General notes, it is the policy of the United States government to encourage other countries to adopt a doctrine of equivalents as healthy as our own. A very recent decision by the High Court in Osaka, Japan shows that Japanese courts are turning to our view. In light of the changes occurring internationally, and encouraged by the United States, it would be ironic for this Court now to limit dramatically a doctrine which is recognized as a cornerstone of United States industrial policy.

Anyone who chooses to practice an invention on the borders of its claims takes a risk. The doctrine of equivalents, which states only that insubstantial alterations to an invention will not eliminate infringement, does little to increase that risk or make it less predictable. Nor does application of the doctrine by juries. Infringement is, and

has always been, a question for the jury. In addition, application of the doctrine should not depend on equitable factors. A rule that allowed only "good" plaintiffs to sue "bad" defendants under the doctrine would promote, rather than lessen, uncertainty.

Petitioner asks this Court to extend the application of prosecution history estoppel, a long-established limit on the doctrine of equivalents, beyond its proper circumstances. Prosecution history estoppel prevents a patentee from using the doctrine of equivalents to recapture subject matter that would not have been patentable over prior art. Petitioner, however, would find an estoppel whenever there was an amendment, regardless of its purpose. As most patent applications are amended, Petitioner's proposal would amount to a de facto elimination of the doctrine of equivalents. Such a rule has no basis in this Court's decisions and would serve no useful purpose.

ARGUMENT

I. THE BIOTECHNOLOGY INDUSTRY DEPENDS ON A HEALTHY DOCTRINE OF EQUIVALENTS.

A. Industries and Inventors Rely on the Doctrine: Abolition or Limitation Would Be a Drastic Change in Patent Law that Should Be Made, If at All, by Congress.

The doctrine of equivalents has been an integral part of the United States patent system for nearly a century-and-a-half, since this Court decided *Winans v. Denmead*, 56 U.S. (15 How.) 330 (1853). In subsequent years, this Court's decisions repeatedly affirmed the vitality of the doctrine and rejected efforts to limit its scope. *See, e.g., Graver Tank & Mfg. Co. v. Linde Air Prods. Co.*, 339 U.S. 605, 608-09 (1950) (collecting cases); *Continental Paper Bag Co. v. Eastern Paper Bag Co.*, 210 U.S. 405, 415 (1908) (refusing

to limit the doctrine's applicability to "pioneer" inventions). Just last month, in *Markman v. Westview Instruments, Inc.*, 64 U.S.L.W. 4263 (U.S. Apr. 23, 1996), this Court again reiterated the importance of the doctrine, noting that a patent claim "functions to forbid not only exact copies of an invention, but products that go to 'the heart of the invention but avoid the literal language of the claim by making a noncritical change.' " *Id.* at 4264 (quoting H. Schwartz, *Patent Law and Practice* 82 (2d ed. 1995)).

The long-established pedigree of the doctrine of equivalents puts individuals on notice that "to copy the principle or mode of operation [described in a patent], is an infringement, although such copy should be totally unlike the original in form or proportions." *Winans*, 56 U.S. at 342; *see also Sanitary Refrigerator Co. v. Winters*, 280 U.S. 30, 42 (1929) (finding infringement "by a device in which there is no substantial departure from the description in the patent"). Patentees and accused infringers alike anticipate that the doctrine will be used to determine questions of infringement. Patentees rely on the doctrine when drafting their claims. Patent attorneys, who interpret patent claims according to familiar rules of patent interpretation, which include a doctrine of equivalents, apply this law every day to ascertain properly the scope of a claimed invention. Potential infringers also must consider the doctrine when evaluating whether to engage in conduct that may infringe a patent.

The decision to practice a patented invention near the borders of its claims is a calculated risk, requiring no more care than in analogous areas of the law. Application of the "substantial differences" test used by the majority of the court below in this case is no less certain, for example, than application of a "reasonableness" test found in ordinary tort law. Parties must make judgment calls, and patent attorneys, schooled in claim interpretation and familiar with the technology involved in the patent, are eminently able to

make such determinations. That they may sometimes be wrong is no reason to eliminate or severely limit the doctrine. They are also sometimes wrong in opining on literal infringement. *See, e.g., Transmatic, Inc. v. Gulton Indus., Inc.*, 53 F.3d 1270, 1278-79 (Fed. Cir. 1995).

Elimination or limitation of the doctrine of equivalents would result in a number of predictable adverse consequences. First, patentees, unable to rely on the doctrine of equivalents, would claim a greater number of variants of their inventions to attempt to gain protection against insubstantial changes. Such additional disclosures could cause an explosion in the verbiage a patent contains. The Court of Customs and Patent Appeals noted that "[t]o require such a complete disclosure would apparently necessitate a patent application or applications with 'thousands' of examples . . . along with information as to whether each exhibits [the property of the invention]." *In re Angstadt*, 537 F.2d 498, 502 (C.C.P.A. 1976). Because the additional information disclosed would consist of insubstantial variations, there would be little corresponding public benefit from this disclosure, if any. Instead of reasonable notice of the scope of claims (including equivalents), competitors would be buried in "an avalanche of trivial information—a result that is hardly conducive to informed decisionmaking." *TSC Indus., Inc. v. Northway, Inc.*, 426 U.S. 438, 448-49 (1976) (finding that financial disclosure in too much detail provides investors less useful information).

Practices in Japan, where patents traditionally have been subject to narrow literal interpretations, substantiate this fear. *See* U.S. General Accounting Office, *Intellectual Property Rights: U.S. Companies' Patent Experiences in Japan*, GAO/GGD-93-126, at 28 (July 1993) ("Under Japanese patent practice, patent claims are construed as narrowly as possible."). Whenever a patent of value is published, competitors of the patentee will file "excessive numbers" of

patents claiming minor variations, a practice known as "patent flooding." *Id.* at 18. Without a doctrine of equivalents, competitors would do the same in the United States, to hem in important inventions and extort a cross-license at an unfair price.

Second, loss of the doctrine of equivalents would provide added incentive for patentees to blur the boundaries of their inventions with broadening terms and imprecise adjectives. *See, e.g., Eibel Process Co. v. Minnesota & Ontario Paper Co.*, 261 U.S. 45, 66 (1923) (using "substantial" and "high" to describe a patentable improvement to a papermaking machine); *Bausch & Lomb, Inc. v. Barnes-Hind/Hydrocurve, Inc.*, 796 F.2d 443, 450 (Fed. Cir. 1986) (claiming a "smooth" contact lens), *cert. denied*, 484 U.S. 823 (1987). *See generally* 2 D. Chisum, *Patents* § 8.03[3][c] (rev. ed. 1995) (discussing words of degree and relational terms). Literal infringement analyses, already difficult, would become more so.

Third, abolition of the doctrine of equivalents would increase the number of claims per patent, increasing the burden on an already overworked PTO. During examination, a patent examiner must evaluate whether each claim is definite, enabled by the specification, and supported by a written description. 35 U.S.C. § 112. In addition, the examiner must compare each claim to the prior art to determine whether the art anticipated or rendered obvious the claim. 35 U.S.C. §§ 102, 103. The additional work created by vastly greater numbers of claims per patent would increase the time from the filing of a patent application to issuance of a patent. The impact on inventors would be exacerbated by the recent change in the term of patent protection, formerly seventeen years from the date the patent issues, now twenty years from the date of filing. Pub. L. No. 103-465, tit. V, § 532(a)(1), 1994 U.S.C.C.A.N. (108 Stat.) 4809, 4983-4984 (1994) (codified as amended at 35 U.S.C. § 154).

Biotechnology patents, which now may take eight or ten years to issue,[2] could well take fifteen years instead, leaving the patentee with only a few years of protection.

If this Court were to limit the doctrine of equivalents, patents obtained in reliance on the doctrine would become valueless. Indeed, very few patents are granted with claims as originally filed. General Accounting Office, *supra*, at 17; *Hughes Aircraft Co. v. United States*, 717 F.2d 1351, 1363 (Fed. Cir. 1983). Many patentees have accepted claim language amendments suggested by the PTO because current law provides adequate coverage and does not create an estoppel. If any change in the law is appropriate, it should be made by Congress, which can adopt appropriate grandfathering legislation.

Lastly, and contrary to the patent law's objective of encouraging the public disclosure of useful inventions, the loss of the doctrine of equivalents would inevitably cause companies to rely more heavily on trade-secret protection for their inventions. "The interest of the public is that the bargain of 17 years of exclusive use in return for disclosure be accepted." *Kewanee Oil Co. v. Bicron Corp.*, 416 U.S. 470, 489 (1974). Faced with uncertainty that their patents may be rendered "hollow and useless" by only strict literal reading, or that prosecution history estoppel would nullify the doctrine, inventors will be forced to limit disclosure of certain inventions, especially in unpredictable arts such as biotechnology. *See Angstadt*, 537 F.2d at 503. The public interest would suffer from the delay in industry's ability to build on patented inventions.

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[2] *See, e.g., In re Ochiai*, 71 F.3d 1565, 1566 (Fed. Cir. 1995) (seventeen years from filing to final rejection by the PTO and three more years for appeal, which allowed the patent to issue); *In re Brana*, 51 F.3d 1560, 1562 & n.2 (Fed. Cir. 1995) (eight years from application to appeals court decision reversing PTO rejection); *Chiron Corp.*, 902 F. Supp. at 1108 (eight years from filing to issuance).

B. Loss of the Doctrine Would Be a Step Backwards in the Movement to Provide Effective International Patent Protection.

It would be ironic for this Court now to cut back the doctrine of equivalents. As the brief of the Solicitor General notes, it has been the policy of the United States government to encourage other countries to adopt an effective doctrine of equivalents like our own. Just recently, a decision by the High Court in Osaka, Japan shows that Japanese courts are turning to our view. *See* T. Takenaka, *New Policy in Interpreting Japanese Patents* (in press, submitted in the appendix to this brief).[3] Genentech, a large United States biotechnology company, sued a Japanese pharmaceutical company for infringing Genentech's Japanese patents for a protein called t-PA, which is comprised of a chain of four hundred thirty-nine amino acids. The Japanese company's product differed from Genentech's claimed invention by only one amino acid and functioned almost identically. Applying traditional Japanese law of infringement, which focuses exclusively on literal claim language, *see* Takenaka, *supra*; General Accounting Office, *supra*, at 28, the Japanese trial court found no infringement. In an opinion that reflects fundamental changes in Japanese patent law, the Osaka High Court reversed, based on reasoning largely similar to that of the majority of the Federal Circuit in the decision below in this case. *See* Takenaka, *supra*. That the rest of the world is adopting policies this Court has long affirmed emphasizes the soundness of U.S. law.[4]

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[3] Dr. Takenaka's remarks, including her translation of the Japanese High Court decision that she discusses, will be published in Volume 3, Issue 2, of the *CASRIP Newsletter* (Summer 1996).

[4] In its 1993 study of patent practice in the United States, Europe, and Japan, the General Accounting Office surveyed over three hundred companies, including top patent holders in the chemical, semiconductor, and biotechnology industries. General Accounting Office, *supra*, at 19. When asked to comment about the patent protection they receive in Japan, 41 percent reported significant problems with the narrow scope given these patents. Only 5 percent, however, criticized the scope of United States patent protection, which includes the doctrine of equivalents. *Id.* at 28. Efforts to harmonize the patent laws of the United States, Europe, and Japan call for Japan to adopt a United States-like doctrine of equivalents, not vice-versa. *Id.* at 73 tbl. 6.2.

C. The Doctrine of Equivalents Is Integral to United States Patent Law and Is Compatible with Particular and Distinct Claiming.

Since 1853, when this Court decided *Winans*, the doctrine of equivalents has been a necessary and integral part of United States patent law. In *Winans*, Justice Curtis, a former patent practitioner, found the doctrine necessary to carry out Congress' constitutional mandate "To Promote the Progress of Science and Useful Arts." U.S. Const., art. I, § 8, cl. 8.

> The exclusive right to the thing patented is not secured, if the public are at liberty to make substantial copies of it, varying its form or proportions. And, therefore, the patentee, having described his invention, and shown its principles, and claimed it in that form which most perfectly embodies it, is, in contemplation of law, deemed to claim every form in which his invention may be copied, unless he manifests an intention to disclaim some of those forms.

Winans, 56 U.S. at 343. The *Winans* majority endorsed the application of the doctrine in the face of the identical arguments now raised by Petitioner and several Amici, that the doctrine of equivalents is inimical to the policy of providing notice about the scope of patent claims. *See id.* at 347 (Campbell, J., dissenting).

Although the doctrine has never been expressly part of any of this nation's Patent Acts,[5] it plays a fundamental role in United States patent laws. As Judge Learned Hand explained:

> [A] boundary [in patent claims] cannot be drawn with precision; and the draftsman of claims is always in something of a dilemma—the dilemma which has led to the very "doctrine of equivalents" itself. . . . On the one hand, if he confines himself rigidly to those elements as they appear in the specifications, he deprives the patent of any practical value, because it is always, or almost always, possible to change the form of these as they appear, and yet cull the full advantage of the discovery. On the other hand, if he too much abandons the elements as they are disclosed, he will not "particularly point out * * * the part * * * or combination which he claims": i.e. he will have so far generalized the disclosure, that the combination of any elements which will effect the same result will be covered. The patent will then pro tanto stifle progress in the art and be invalid. It is impossible in practice to emerge from this embarrassment without some measure of compromise; the elements as they appear in the claims must be clearly enough identified with elements as they appear in the manifold to be "substantially" limited by their description, verbal and pictorial. Yet

[5]The Patent Acts have never expressly proscribed "literal" infringement either. The relevant section of the current Act says only that "whoever without authority makes, uses, offers to sell or sells any patented invention . . . infringes the patent." 35 U.S.C. § 271(a). The Act defines "invention" through section 112, which states that an applicant must claim "the subject matter which the applicant regards as his invention." 35 U.S.C. § 112.

> the claims must be given enough scope to cover "substantially similar" variants.

Royal Typewriter Co. v. Remington Rand, Inc., 168 F.2d 691, 693-94 (2d Cir.), *cert. denied*, 335 U.S. 825 (1948).

Petitioner argues that the doctrine of equivalents is incompatible with the current Patent Act, particularly with 35 U.S.C. section 112, which requires that a patentee "particularly point[ ] out and distinctly claim[ ]" his invention. There is no incompatibility. As the Federal Circuit, which has special expertise in this area, has explained, a patentee can only draft claims that are "as precise as the subject matter permits." *See, e.g., North Am. Vaccine, Inc. v. American Cyanamid Co.*, 7 F.3d 1571, 1580 (Fed. Cir. 1993), *cert. denied*, 114 S. Ct. 1645 (1994); *see also Eibel Process*, 261 U.S. at 65-66. It may not be possible to describe the inventor's technical concept with absolute precision, and a patent's claims will be allowed if they "'reasonably apprise those skilled in the art of the scope of the invention.'" *Credle v. Bond*, 25 F.3d 1566, 1576 (Fed. Cir. 1994) (quoting *Miles Labs., Inc. v. Shandon, Inc.*, 997 F.2d 870, 875 (Fed. Cir. 1993)).

Section 112, then, establishes only a "reasonableness" standard for claim precision, one that must be evaluated according to the facts and circumstances of each case. This "reasonableness" standard would be inconsistent with a legal regime that did not allow for infringement by equivalents. No purpose would be served by a requirement for "reasonable" precision in the description of an invention if the law also required absolute identity between the claims and the accused device for a finding of infringement.

D. The Public Interest in Biotechnology Development Would Be Impaired If the Doctrine Were Eliminated or Cut Back.

"The biotechnology industry has been one of the success stories in U.S. industry, creating new jobs and pioneering exciting breakthroughs that improve our way of life." 141 Cong. Rec. S15221 (daily ed. Oct. 17, 1995) (statement of Sen. Hatch). "In 1994, sales of biotechnology products totaled close to $8 billion, and the Department of Commerce estimates that biotechnology will be a $50 billion industry by the year 2000." 141 Cong. Rec. S7300-01 (daily ed. May 24, 1995) (statement of Sen. Harkin). Biotechnology products include insulin to treat diabetes, drugs to treat AIDS and cancer, human growth hormone to treat dwarfism, and diagnostic tests to ensure the safety of the world's blood supply against viruses such as those causing hepatitis and AIDS.

"The biotechnology industry relies heavily on patent protection in recouping the costs of bringing new drugs to the market. Furthermore, adequate patent protection is vital in persuading investors to provide the necessary capital to the industry." 141 Cong. Rec. S15221 (daily ed. Oct. 17, 1995) (statement of Sen. Hatch). Cutting back the doctrine of equivalents would devastate the biotechnology industry's capacity to protect the value of its inventions. Any such change would dramatically inhibit the industry's ability to conduct the extensive research and development required to deliver new life-saving products to the public.

To understand the importance of the doctrine of equivalents to biotechnology patents, a modicum of background in biology is helpful.[6] All living organisms contain genetic material, usually made of DNA (deoxyribonucleic acid). Smaller molecules, called nucleotides, are arranged in a DNA molecule like

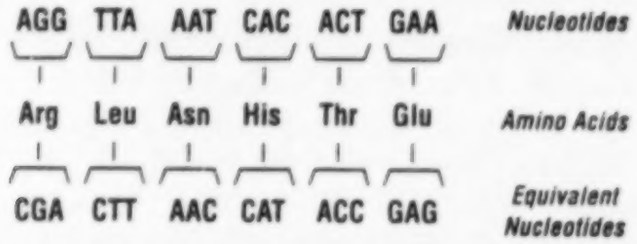
[6]For additional background, see K. Drlica, *Understanding DNA and Gene Cloning: A Guide for the Curious* 27-37 (2d ed. 1992).

beads on a string. Only four nucleotides, typically labeled A, T, C, and G, comprise DNA, but a single strand of DNA may have thousands or millions of nucleotides.

DNA contains encoded information that living cells use to build proteins. Proteins are molecules that help to perform a wide variety of functions in living organisms, from digesting food to forming muscles to helping the immune system combat infections. Like DNA, proteins can be described as linear (chain-like) molecules. All protein chains are made from combinations of twenty smaller molecules, called amino acids. The sequence of nucleotides in DNA "encodes" the sequence of amino acids in a protein. Each group of three nucleotides in a DNA sequence "codes" for one amino acid. In this way, a long molecule of DNA describes a long protein molecule. Living cells have a complex machinery that "reads" a molecule of DNA, taking the sequence information from the DNA molecule and building the corresponding protein. A "gene" is simply a sequence of DNA that encodes for a particular protein.

The doctrine of equivalents is essential for biotechnology patents claiming particular genes or proteins. In biotechnology patent cases, the Federal Circuit has developed a rule that an inventor cannot claim a gene without disclosing its sequence. *Fiers v. Revel*, 984 F.2d 1164, 1170 (Fed. Cir. 1993); *Amgen, Inc. v. Chugai Pharmaceutical Co.*, 927 F.2d 1200, 1206 (Fed. Cir.), *cert. denied*, 502 U.S. 856 (1991). Thus, under the law that the PTO applies during biotechnology patent examinations, it is impossible to write a valid claim for "a DNA sequence encoding protein X" unless the specification to the patent discloses that the sequence AGGTTAAATCAC etc. encodes protein X. Therein lies the rub. Because there are sixty-four combinations of three nucleotides (recall that three nucleotides encode one amino acid) and only twenty amino acids, several different combinations of nucleotides are known to encode for the same

amino acid. For example, nucleotides AGG and CGA both code for the same amino acid. Thus, two very different strands of DNA can encode the same amino acid sequence:



So, too, for proteins: certain individual amino acids are interchangeable without effect on some functions of a protein. *See* Takenaka, *supra*.

Without a doctrine of equivalents, a gene patent would be valueless unless it claimed every equivalent sequence of nucleotides — competitors could infringe at will simply by substituting nucleotides with others known to be interchangeable. The mathematics alone, however, make describing every possible variant impractical. *See In re Bell*, 991 F.2d 781, 784 (Fed. Cir. 1993) (noting that 10^{36} nucleotide sequences encode a protein called IGF). While no doubt a computer could be programmed to print out every analog, the resulting patent claims would be a stack of paper many miles high, and would overwhelm the PTO, as well as those who track patents, with their sheer bulk.[7]

Protein patents present a similar problem. As the Federal Circuit noted in analyzing a patent claim to the protein erythropoietin, "over 3,600 different [protein] analogs can be made by substituting at only a single amino acid position, and over a million different analogs can be made by substituting three amino acids." *Amgen*, 927 F.2d at 1213. Many analogs are functionally indistinguishable, and no purpose would be served by requiring their disclosure.

[7]The difficulties of examining DNA and protein patents have already forced the PTO to adopt special rules in this area. 37 C.F.R. §§ 1.821 et seq. (1995); U.S. Department of Commerce, Patent & Trademark Office, *Manual of Patent Examining Procedure* §§ 2420 et seq. (rev. ed. Sept. 1995).

Biotechnology also needs a doctrine of equivalents to allay unpredictability in application of the law concerning the breadth of claims allowable under section 112. An applicant who isolates a particular protein may, for example, claim that protein. In addition, he or she may identify particularly useful protein fragments, and claim those as well. The patentee may then attempt to claim all similar protein fragments generally. Whether the PTO or courts will allow such a claim depends on an eight-factor test, described by the Federal Circuit in *In re Wands*, 858 F.2d 731 (Fed. Cir. 1988). The factors include:

> (1) the quantity of experimentation necessary [to make the claimed invention], (2) the amount of direction or guidance presented [in the specification], (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims.

Id. at 737. Stating the test emphasizes the difficulty an inventor faces at the time of application in predicting whether the claims will be allowed based on the patent's specification. *See Amgen*, 927 F.2d at 1212-14. As a result, section 112 alone, without any prior art, can severely limit claims.

Without a doctrine of equivalents to temper this unpredictability, decisions in the PTO based on the *Wands* test could cut off legitimate rights to claim an invention and its substantial equivalents. An inventor's only protection against these losses would be to make and test each potentially useful variant and to describe each in his specification. The extra work would slow down patent applications and would

divert the industry's resources from developing the best commercial embodiments of its inventions.

E. Equivalents Must Include Later-Discovered Equivalents.

The special problems in biotechnology highlight the need for a doctrine of equivalents that includes equivalents discovered after a patent is filed. The example described in the appendix to this brief illustrates this point. Genentech obtained a patent for t-PA, which is made up of four hundred thirty-nine amino acids. One of Genentech's competitors later discovered that substituting the amino acid methionine for the amino acid valine as the protein's two hundred and forty-fifth amino acid created a protein with functionally identical biological properties. Without a doctrine of equivalents, the value of Genentech's patent would have been lost, even though the substitution of methionine for valine creates a molecule which is, for all known relevant biological purposes, the "same" protein.

Later-discovered improvements also should not preclude a finding of infringement by equivalents. Additional research on t-PA could show, for example, that all but the last fifty of the molecule's four hundred thirty-nine amino acids make up the part of the molecule with therapeutic uses, and that cutting off the last fifty amino acids lowers the molecule's cost of manufacture by making the molecule more soluble. That discovery may itself be patentable. *See Tilghman v. Proctor*, 102 U.S. 707, 724-25 (1880). Nevertheless, one using t-PA without its last fifty amino acids is still using t-PA and still exploiting the basic discovery of t-PA.

Later-discovered equivalents and improvements in biotechnology are most likely for pioneer patents, which open up new avenues of research. Loss of the doctrine of equivalents in such cases would lead to the ironic result that pioneer patents would receive less protection than merely

incremental inventions, instead of the full protection to which they are entitled. *See Brothers v. United States*, 250 U.S. 88, 89 (1919) (noting that pioneer patents are "entitled . . . to a liberal application of the doctrine of equivalents"); *Continental Paper Bag*, 210 U.S. at 415.

A doctrine of equivalents that established a per se rule based on distinctions between noninfringing improvements and infringing equivalent alterations would unfairly eliminate patentees' property rights. It would also be arbitrary. The distinction between these concepts inevitably turns on facts unique to each case. *Compare Miles Labs.*, 997 F.2d at 877 *with Texas Instruments, Inc. v. United States Int'l Trade Comm'n*, 805 F.2d 1558, 1571 (Fed. Cir. 1986). Any attempt by this Court to fashion a rigid rule based on an improvement/alteration distinction would only exacerbate the uncertainty already inherent in infringement analysis.

F. Absolute Certainty in Claim Interpretation Is an Unattainable Goal.

Petitioner and several Amici argue that by eliminating the doctrine of equivalents this Court would return certainty to questions of infringement. They also suggest that the doctrine of equivalents is unnecessary, or can be drastically limited, because patentees could protect themselves against too narrow literal infringement findings simply by claiming their inventions with more care.

These arguments imply that there is little or no uncertainty in a literal infringement analysis. This is demonstrably wrong. The inherent limits in the ability of language to describe inventions create an inevitable amount of uncertainty at the borders of patent claims, whether the infringement asserted is literal or equivalent. In *Hoechst Celanese Corp. v. BP Chems. Ltd.*, 78 F.3d 1575 (Fed. Cir. 1996), the patent-at-issue claimed a method for reducing iodide contamination in an organic medium. The method requires a

"stable" resin. *Id.* at 1578. The specification of the patent defined "stable" to mean "that the resin will not chemically decompose, or change more than about 50 percent of its dry physical dimension upon being exposed to the organic medium. . . ." *Id.* at 1578-79.

Despite the detail in this definition, Hoechst and BP, both sophisticated parties, hotly disputed the literal meaning of "stable." The particulars of the dispute are unimportant to this discussion. What matters is that these two large chemical companies, and their patent counsel, each felt that a literal reading of "stable" led to a literal infringement finding in its favor.

Disputes such as these are inevitable, especially when words in a document are used to describe new technology.

> An invention exists most importantly as a tangible structure or a series of drawings. A verbal portrayal is usually an afterthought written to satisfy the requirements of patent law. This conversion of machine to words allows for unintended gaps which cannot be satisfactorily filled. Often the invention is novel and words do not exist to describe it.

Autogiro Co. of Am. v. United States, 384 F.2d 391, 396-97 (Ct. Cl. 1967). Loss of the doctrine of equivalents would give patent attorneys added incentive to blur the borders of their claims with broadening terms and imprecise adjectives. Infringement evaluations would become more uncertain, not less.

II. DETERMINATION OF INFRINGEMENT UNDER THE DOCTRINE OF EQUIVALENTS IS A QUESTION OF FACT, BASED ON OBJECTIVE CRITERIA, THAT MUST BE TRIED TO THE JURY.

A. Infringement Is a Question for the Jury.

Determination of infringement by equivalents is a question of fact, historically left to juries. Some have argued that the application of the doctrine of equivalents is an equitable "remedy," granted by the court under certain circumstances, or a matter of claim construction, also for the court. Those arguments, based on a misconception of the doctrine, are incorrect.

The doctrine of equivalents recognizes that, in patent law, "'if two devices do the same work in substantially the same way, and accomplish substantially the same result, they are the same, even though they differ in name, form, or shape.'" *Graver Tank*, 339 U.S. at 608 (quoting *Machine Co. v. Murphy*, 97 U.S. 120, 125 (1877)); *see also Sanitary Refrigerator*, 280 U.S. at 41-42 ("There is a substantial identity, constituting infringement," where a device copies a claimed device, without variations *or* with such variations "'as are consistent with its being in substance the same thing.'") (quoting *Burr v. Duryee*, 68 U.S (1 Wall.) 531, 573 (1863)). Therefore, a device or product which does not literally infringe a claim may be an infringement nonetheless, because a claim "functions to forbid not only exact copies of an invention, but products that go to 'the heart of the invention but avoid the literal language of the claim by making a noncritical change.'" *Markman*, 64 U.S.L.W. at 4264 (quoting Schwartz, *supra*, at 82).

A cause of action of infringement by equivalents is not an equitable remedy, nor any sort of "remedy" at all. Nor is it, as some have argued, analogous to contract reformation. Application of the doctrine does not require a search for

errors made in drafting the claim, so that the claim can be reformed. Instead, it allows for the inherent limitations of language by recognizing that "the substantial equivalent of a thing, in the sense of the patent law, is the same as the thing itself. . . ." *Machine Co.*, 97 U.S. at 125. No matter how carefully drafted, words can never describe a claim so completely and precisely that it encompasses all possible variations. Therefore, it is fair and just to provide protection not only to the exact language of the claim, but also to its substantial equivalents. That is the only sense in which the doctrine of equivalents is equitable.

Arguments made by Petitioner and Amici suggest that the doctrine of equivalents requires two different constructions of the claim. Such arguments are wrong. Application of the doctrine of equivalents arises after the court construes the claim, during the comparison of the claim as construed with the accused device or process. Consideration of that evidence is part of the factual determination of whether or not infringement occurred. If the evidence shows that the accused device is identical to a device literally described by the claim, literal infringement is established, and the comparison is finished. If the accused device is not identical, the fact-finder considers the evidence to determine the substantiality of the differences between the accused device and one that would be literally infringing. If the differences are insubstantial, infringement by equivalents is established. Both of these determinations are questions of fact.

This Court has held consistently for nearly one hundred and fifty years that determination of infringement by equivalents is a factual question for the jury. *See Royer v. Schultz Belting Co.*, 135 U.S. 319, 325 (1890); *Tyler v. Boston*, 74 U.S. (7 Wall.) 327, 330-31 (1868); *Winans*, 56 U.S. at 344. Less than a month ago, this Court explained again that issues of product identification, that is, "'questions of identity and diversity of inventions,'" are properly

reserved for the jury. *Markman*, 64 U.S.L.W. at 4268 (quoting *Bischoff v. Wethered*, 76 U.S. (9 Wall.) 812, 816 (1870)). Allowing the court to make an "initial" determination that the diversity between the claim and the accused product or process is insubstantial, as has been suggested,[8] would completely usurp the role of the jury. Once the judge has considered the evidence and decided as a matter of fact that the differences are insubstantial, nothing is left for the jury to do. Just as it would be improper (as it was in *Bischoff*) for the court to compare the claim and the accused device or process to determine whether as a matter of fact there *are* any differences, it would be improper for the court to compare them to determine whether as a matter of fact any differences are *insubstantial*. That sort of dispositive role for the court is precisely what this Court warned in *Markman* "would improperly eliminate the jury's function in answering the ultimate question of infringement."[9] *Markman*, 64 U.S.L.W. at 4267.

Some of those who argue for the elimination of the jury seem to be motivated by a belief that patent infringement cases are too complicated for juries. That is not a new complaint. One hundred twenty-four years ago, in *Tucker v. Spalding*, 80 U.S. (13 Wall.) 453 (1872), this Court held

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[8]This proposition was made in one of the dissenting opinions in the lower court, which recognized that the assessment made by the judge would overlap "in considerable degree" with the analysis to be applied by the jury. *Hilton Davis Chem. Co. v. Warner-Jenkinson Co.*, 62 F.3d 1512, 1544 (Fed. Cir. 1995) (Plager, J., dissenting).

[9]Affirming that the judge must not make the factual determinations about the substantiality of differences does not mean that every case where infringement by equivalents is alleged will get to the jury. To the contrary, as the Federal Circuit clearly has established, the patentee must offer admissible objective evidence of infringement. *See, e.g., Hilton Davis*, 62 F.3d at 1519. If the evidence is lacking, such that a reasonable jury could not find infringement by equivalents, summary judgment is appropriate.

"[w]hatever may be our personal opinions of the fitness of the jury as a tribunal to determine the diversity or identity in principle of two mechanical instruments, it cannot be questioned that . . . that question must be submitted to the jury, if there is so much resemblance as raises the question at all." *Id.* at 455. Patent cases may be complicated. Other types of cases are complicated, too, but we do not take them from the jury for that reason. The solution to complexity is not to eliminate the jury, but to present the evidence in such a way that the jury can understand it.

B. The Existence of Infringement by Equivalents Should Be Based on Objective Criteria.

Those who would misconstrue the doctrine of equivalents as an equitable remedy would have courts condition the applicability of the doctrine on subjective criteria such as the good behavior of the patentee or the ill intent of the alleged infringer. That argument is inconsistent with the strict liability aspect of patent law, which does not make liability for infringement dependent on intent to infringe. 35 U.S.C. § 271(a). The law places the responsibility to determine if an existing patent is being infringed on those who are developing devices or products in a particular field. Patents are publicly available so that anyone can determine if a particular device or process has been patented. Liability for infringement is avoided by taking care to avoid it, not by ignoring the possibility of infringement. Liability should not change just because a particular "innocent" infringer was fortunate enough inadvertently to avoid literal infringement by having made insubstantial changes. Such a result would be inconsistent with the policy of providing uniform protection for patents.

The argument that only deliberate copiers should be liable for infringement by equivalents is also contrary to the purpose of the doctrine itself. The doctrine protects "the

heart of the invention" from infringement through insubstantial changes. It guards against infringement by one who is either clever or lucky enough to include an element that uses the patented idea but avoids the exact words of the claim. The doctrine is concerned with protecting the property rights of the patentee, not with punishing infringers.[10] The protection given through application of the doctrine would be severely diminished if it were applied only to those who intentionally infringed.[11]

Evidence of deliberate copying versus independent development is not irrelevant to infringement by equivalents. Evidence that an alleged infringer studied the patent and then made only the changes necessary to avoid the literal scope of the patent could allow the fact-finder to draw an inference that the differences are insubstantial. Evidence that the alleged infringer undertook significant independent research and development could allow the contrary inference. Neither type of evidence would be conclusive, however, as under the rules established by the expert judges of the Federal Circuit, the determination of infringement by equivalents depends on the objective differences between the claim and the accused device or process. *Hilton Davis*, 62 F.3d at 1519.

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[10] Punishment of infringers is found elsewhere in patent law. Under 35 U.S.C. sections 284 and 285, the court may award a patentee enhanced damages and attorney fees if the infringer is shown to have acted in bad faith. Those sections do not distinguish between literal and equivalent infringers, but apply to both.

[11] The Court's reference in *Graver Tank* to an "unscrupulous copyist" was not a restriction on the application of the doctrine, but only a recognition that the need for application of the doctrine is particularly apparent where such infringers appear. *Graver Tank*, 339 U.S. at 607, 612.

III. AS MOST APPLICATIONS ARE AMENDED, ADOPTING PETITIONER'S POSITION ON PROSECUTION HISTORY ESTOPPEL WOULD RESULT IN A DE FACTO ELIMINATION OF THE DOCTRINE OF EQUIVALENTS.

Prosecution history estoppel is a well-established limitation on the scope of permissible equivalents to a patent claim. In applying principles of prosecution history estoppel established by this Court, the Federal Circuit, which reviews dozens of prosecution histories each year, has established an appropriate balance between the property interests of the patentee and the reliance interests of accused infringers.[12] This case presents no reason to rewrite this law.

Petitioner essentially asks this Court to expand the application of prosecution history estoppel to preclude a patentee's resort to the doctrine of equivalents whenever claims are amended during prosecution. Although Petitioner couches its argument in terms of "deliberate surrenders," as a practical matter, any narrowing amendment could be characterized in later litigation as a surrender. Were the Court to adopt Petitioner's "surrender" approach to prosecution history estoppel, any patentee who amended his claims would be unable to rely on the doctrine of equivalents. Since most patent applications are amended after filing, General Accounting Office, *supra*, at 17, Petitioner is, in fact, seeking a de facto elimination of the doctrine of equivalents. This result is not compelled either by this Court's precedents or by the policies behind prosecution history estoppel.

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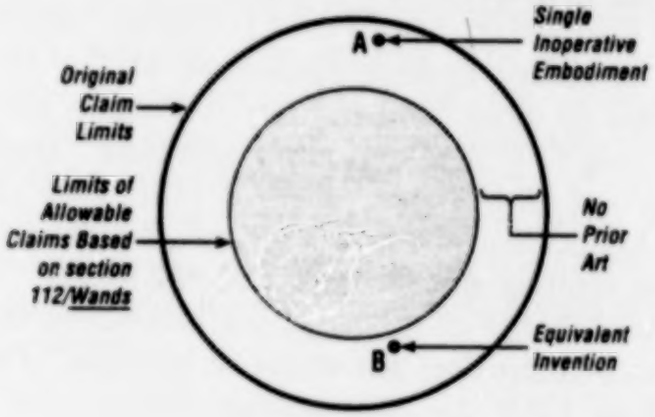
[12] *See Hoganas AB v. Dresser Indus., Inc.*, 9 F.3d 948, 952 (Fed. Cir. 1993) (measuring estoppel "from the vantage point of what a competitor was reasonably entitled to conclude, from the prosecution history, that the applicant gave up to procure issuance of the patent"); *see also Haynes Int'l, Inc. v. Jessop Steel Co.*, 8 F.3d 1573, 1578 (Fed. Cir. 1993), *on reh'g*, 15 F.3d 1076 (Fed. Cir. 1994) (same).

This Court's precedents have made clear that when, as in *Hilton Davis*, a patent applicant surrenders subject matter during patent examination to overcome an objection based on prior art, the patentee cannot use the doctrine of equivalents to recapture subject matter that was not patentable in the first instance. *Exhibit Supply Co. v. Ace Patents Corp.*, 315 U.S. 126, 136 (1942) (prosecution history estoppel applies when an applicant alters his claims "in order to meet objections in the Patent Office, based on references to the prior art"); *Smith v. Magic City Kennel Club, Inc.*, 282 U.S. 784, 789 (1931) ("where an applicant for a patent to cover a new combination is compelled by the rejection of his application by the Patent Office to narrow his claim by the introduction of a new element, he cannot after the issue of the patent broaden his claim by dropping the element"); *I.T.S. Rubber Co. v. Essex Rubber Co.*, 272 U.S. 429, 443 (1926) (same). A more expansive view of the doctrine is not warranted.

As the Federal Circuit has noted, "in the course of patent examination claims are often amended and rewritten and added and subtracted." *Pall Corp. v. Micron Separations, Inc.*, 66 F.3d 1211, 1219 (Fed. Cir. 1995). "No reason or warrant exists for limiting application of the doctrine of equivalents to those comparatively few claims allowed exactly as originally filed and never amended." *Hughes Aircraft Co. v. United States*, 717 F.2d 1351, 1363 (Fed. Cir. 1983). Application of the *Wands* test, for example, often results in limiting amendments. For this reason, "[a] nonsubstantive change or a change that did not in fact determine patentability does not create an estoppel." *Pall Corp.*, 66 F.3d at 1219; *see also Musher Found., Inc. v. Alba Trading Co.*, 150 F.2d 885, 888 (2d Cir.) (L. Hand, J.) (when a patentee's amendment is not to overcome prior art "it becomes an open question which must be proved, whether he intends to surrender the disclosure in such sense

that he abandons any equivalents of the elements of those claims which he keeps"), *cert. denied*, 326 U.S. 770 (1945).

Petitioner's position on prosecution history estoppel ignores its purpose, and would apply prosecution history estoppel in even those cases in which an amendment was not required to overcome prior art. *Graver Tank* itself suggests circumstances in which this could occur. The patent-at-issue in *Graver Tank* originally contained broad claims that read literally on the defendant's infringing process as well as narrow claims that did not. *Graver Tank*, 339 U.S. at 616 (Black, J., dissenting). The broad claims were found unpatentable because they covered inoperable embodiments. *See Graver Tank & Mfg. Co. v. Linde Air Prods. Co.*, 336 U.S. 271, 276-77 (1949). Nevertheless, in finding infringement of the narrow claims under the doctrine of equivalents, the majority of this Court acknowledged a zone of patent coverage that was broader than the literal language of the claims, but which was not unpatentable over the prior art, and could therefore be infringed. The same situation could arise through an amendment during patent prosecution.



As this diagram illustrates, a patentee may be forced to limit his claims under the enablement requirement of section 112 to only a portion of the full scope of his invention. This could occur, as in *Graver Tank*, if the original claims

contained inoperative embodiments. If the next broadest claim the applicant files consistent with the requirements of section 112 is substantially narrower than the original claim, the claims will be limited to a narrow scope, even though a broader invention scope is allowable over the prior art.[13] Petitioner would have this Court adopt a rule allowing anyone to commercialize "B" without any liability to the patentee, depriving the patentee of the benefits of his invention and chilling patent law's incentives for research.

Petitioner's prosecution history estoppel position creates odd justice. An applicant who filed narrow claims, and received no rejections, would be entitled to the full range of equivalents. An applicant who submitted broad claims, and narrowed them during examination, would get no protection against equivalents, even though the narrower claims are *the same* as would have been allowed in the first instance.

Rigid application of prosecution history estoppel would also flood the courts with PTO appeals. Applicants, reluctant to risk the estoppel effect of narrowing amendments, would have newfound incentive to litigate examiner's decisions. The result would be increased administrative expense for the entire patent system, from the examiners through the Board of Patent Appeals and into the courts. Patent attorneys well understand the application of prosecution history estoppel, which this Court and the Federal Circuit have clearly described. No new rules are needed.

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[13] A patentee is not free to amend claims in any manner he or she desires. Section 112 requires support in the application *as filed* for each claim limitation. For example, if a patentee has claimed a process with a temperature range from 25° to 75°, the patentee may not limit that claim to a range of 30° to 60° unless the application as filed also disclosed the latter specific range. Merely being within the originally disclosed range is not sufficient to satisfy section 112. *See* 2 Chisum, *supra*, at § 7.04[2].

CONCLUSION

The doctrine of equivalents plays an important role in patent law, and is particularly crucial for the biotechnology industry. The loss or limitation of the doctrine would harm the industry without adding any certainty to claim interpretation. The decision of the court below should be affirmed.

Respectfully submitted,

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APPENDIX

New Policy in Interpreting Japanese Patents: Osaka High Court Affirming Infringement of Genentech's t-PA Patents under the Doctrine of Equivalents

Toshiko Takenaka*

On March 29, 1996, Osaka High Court reversed Osaka District Court's decision and found that Sumitomo's t-PA infringes Genentech's pioneer patents for human t-PA under the doctrine of equivalents. Since this case may change Japanese case law on patent claim interpretation 180 degrees to merge with German and U.S. case law, I have included a summary of the case as well as my comments in comparative law aspects.

Decision of Osaka High Court (Osaka Koto Saibansho)
March 29, 1996-Case No. Heisei 6 (ne) 3292

Background

The plaintiff-appellant, who owns two patents for a human tissue plasminogen activator (t-PA), sued the defendant, who was preparing to manufacture and sell a human tissue plasminogen activator, in order to prevent defendant

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from engaging such manufacture and sale. Claims of Patent A issued to the plaintiff read:

1. A recombinant human tissue plasminogen activator resulting from a non-human host cell, having no other human protein, which activator is characterized by

(1) a function to convert plasminogen to plasmin;

(2) an ability to provide an affinity for fibrin;

(3) an ability to immunoprecipitate with antibody against human tissue plasminogen activator originating from Bowes melanoma cell line;

(4) an amino acid sequence providing a kringle region and serine protease region; and

(5) either single or multiple amino acid; and

comprises a segment of 89th to 527th amino acid as indicated in the appendix 1.

2. A method for manufacturing a recombinant human tissue plasminogen activator having no other human protein, comprising steps of culturing non-human host cell transformed with a DNA sequence encodinghuman tissue plasminogen under conditions to enable said host cell to express said DNA; whereby providing a recombinant human tissue plasminogen activator characterized by

(1) a function to convert plasminogen to plasmin;

(2) an ability to provide an affinity for fibrin;

(3) an ability to immunoprecipitate with antibody against human tissue plasminogen activator originating from Bowes melanoma cell line;

(4) an amino acid sequence providing a kringle region and serine protease region; and

(5) either single or multiple amino acid; and

comprises a segment of 89th to 527th amino acid as indicated in the appendix 1; and recovering said recombinant human tissue plasminogen activator.

3. A medicine for the treatment of thrombosis comprising an amount of recombinant human tissue plasminogen activator resulting from a non-human host cell, having no other human protein, which amount is sufficient for such treatment and mixed with a carrier permissible as a medicine, which activator is characterized by

(1) a function to convert plasminogen to plasmin;

(2) an ability to provide an affinity for fibrin;

(3) an ability to immunoprecipitate with antibody against human tissue plasminogen activator originating from Bowes melanoma cell line;

(4) an amino acid sequence providing a kringle region and serine protease region; and

(5) either single or multiple amino acid; and

comprises a segment of 89th to 527th amino acid indicated in the attached appendix 1.

The only claim of Patent B read:

> A microorganism, yeast, and mammal cell transformed by a recombinant expression vector containing a DNA sequence encoding human tissue plasminogen activator, having a sequence of 1st to 527th amino acids listed in the attached appendix 1.

The defendant requested a trial of nullity on both patents but the request was rejected by the Japanese Patent Office. Plaintiff sued another Japanese pharmaceutical company for infringement of the same patents. The Osaka District Court found for plaintiff because that company's t-PA included a sequence of amino acids as they are listed in the claims although the sequence also included some insignificant

amino acids. In contrast, the same court found no infringement for this case since one amino acid was different from the claimed sequence. The court rejected to look at sources other than the claims, stating that it is not necessary to make reference to other sources when the invention is clear from the claim language. Since one amino acid is missing from defendant's t-PA, the court did not find literal infringement. It also rejected plaintiff's request to apply the doctrine of equivalents, emphasizing on the third parties' interests, relying on the claims. The plaintiff appealed, arguing that the defendant's product was substantially the same or equivalent to the patented invention.

In determining equivalency, the parties' arguments focused on the obviousness of replacing valine with methionine, because the replacement is the only structural difference between the patented inventions and the defendant's product. The plaintiff emphasized that the patented inventions are pioneer inventions. To establish non-equivalency, the defendant argued that its t-PA was developed independently from the patented inventions.

Opinion

The contested decision is set aside and the defendant-appellee is sustained from engaging in infringing activities. The plaintiff-appellant's appeal is admissible.

I. Infringement by Equivalents

As arguments by the parties indicate, it is not automatically clear whether the invention including met-t-PA is substantially the same as the invention including val-t-PA. Since an invention is defined as a highly advanced creation of technical idea using a law of nature, courts must put weight on experts' (those skilled in the art) opinions and views in deciding whether an accused embodiment falls within the technical scope provided in Article 70. Unless the

experts can understand the technical scope of the patented invention with no uncertainty on the basis of the claim, claim language is not the only resort for determining the technical scope of a patented invention. Although an invention, which is the subject matter of a patent, i.e., an industrial property right, is described in a claim, the content described in claims is simply the gist of the invention. Since an invention is intangible, its structure must be described in terms of words. It should be noted that although Article 70 provides a means with which to decide the technical scope of the invention on basis of claim language, but does not limit the scope to only cover the literal scope of the claim. Because it is impossible to fully describe the structure of an intangible subject in terms of words, Article 70 provides courts with the flexibility to decide the scope in granting an injunction based on a patent, on the basis of the claim language. The question of whether an accused embodiment falls within the technical scope of a patented invention is a step to define the outermost boundary of the technical scope and is solved by the court which decides infringement.

If an accused embodiment corresponds to the claimed invention and thus is clearly found by one skilled in the art to fall within the technical scope, patent law requires a method for determining the technical scope of a patented invention. This enables courts to find such embodiment being equivalent to the patented invention, even if the embodiment neither literally infringes the claim, nor meets every element of the claim.

In affirming infringement by an embodiment which is not literally the same as the structure of patented invention, courts must pay attention to third parties' interests which rely on the technical scope based on the claim language in balance with the patentee's interest. It is necessary to establish a standard to balance both interests. In scholarly opinions, two elements of interchangeability and obvi-

ousness of interchangeability are proposed as requirements to find equivalency to establish such a standard. Therefore, the parties' dispute in this case centers on whether the accused product meets the two elements. These two elements are positive requirements to affirm equivalency. On the other hand, there are other elements in particular cases, such as some facts in patent prosecution which may prevent courts from finding equivalency. In determining whether the defendant's t-PA including met-t-PA is equivalent to Patented Invention A or B including val-t-PA, courts must affirm equivalency by examining every positive and negative element, while confirming that finding of equivalency would not upset the balance between interests of third parties, who rely on the description of the claims, and those of patentees.

II. Evaluation With Respect To Positive Elements for Equivalents

1. Interchangeability

It is not disputed that all amino acid sequence in patented t-PA and defendants' t-PA are exactly the same, except that the 245th amino acid in Patented Inventions A and B is valine, whereas the corresponding acid in the defendants t-PA is methionine. The defendant also does not dispute that its t-PA has the characteristics cited in the claims of Patents A and B. Accordingly, the defendant's t-PA provides the same function as the patented t-PA, and thus satisfies the interchangeability element.

2. Obviousness of Interchangeability

(Courts listed 11 expert opinions obtained from distinguished professors in molecular biology.)

Expert Opinions

In summary, the experts' opinions on whether one skilled in the art would have readily obtained the defendant's thrombolytic agents by replacing valine with methionine is as follows:

(1) Valine and methionine behave similarly in structuring three dimensional protein structure.

(2) Transformation from valine to methionine in protein amino acid sequences occurs relatively frequently. This transformation does not affect the function of the protein (trivial transformation).

(3) t-PA's 245th position is buried in the hydrophobic region of the three dimensional structure of the protein and has no significant role in relation to biological activity.

(4) If a sequence of amino acids is identified, one skilled in the art could have manufactured a t-PA variation wherein some amino acid residues are replaced, deleted or added by manufacturing t-PA's cDNA and changing a segment of the canonical amino acid sequence in the t-PA.

(5) The significance of Patented Inventions A and B is to express a t-PA cDNA encoding a recombinant t-PA which provides a biological activity.

(6) In scientists' view, the significance of the first successful cloning of a t-PA c-DNA and producing a recombinant t-PA is vastly greater than subsequently repeating the cloning of t-PA by making reference to the disclosure of the first cloning procedure.

(7) Production of a different form of t-PA by making reference to amino acid sequence of t-PA has no practical use, unless the different form of t-PA provides improved characteristics.

(8) Cloning errors occur very frequently. In most cases, such errors result from replacements of insignificant amino acid residues with similar amino acid residues which do not affect the function of the protein. When a protein resulting from a cloning error has the same function as that of the original protein, the error results from a replacement of insignificant amino acids with similar amino acids. Therefore, one skilled in the art could have known that the protein in a different form resulting from the error would have the same function as the original protein.

Technical Objective of Patented Inventions A and B

On the priority date of Patented Inventions A and B, natural t-PA was only produced by isolating from human cells, and the quantity produced by this isolation was very small. Although production of useful proteins through recombinant DNA technology was about to become a reality, the production of t-PA through recombinant DNA technology was very difficult, because an only very small quantity of natural t-PA is available, the concentration of t-PA mRNA is extremely low; and t-PA mRNA consists of a very long sequence. Based on the state of art as discussed, the objective of Inventions A and B is to produce a sufficient quantity of t-PA through a recombinant DNA and to develop t-PA thrombolytic agents. Inventions A and B achieved the objective by determining the sequence of a full-length t-PA clone, which is essential to produce t-PA through recombinant DNA technology. This results in information disclosure which enables one skilled in the art to produce a sufficient quantity of t-PA which is capable of replacing natural t-PA, a sufficient quantity of t-PA to conduct animal and clinical experiments for governmental approvals to commercialize t-PA as medicine.

Significance of Inventions

With respect to the objective, the significance of Inventions A and B relies on a form of t-PA, *i.e.*, an invention of a product, obtained through a recombinant DNA technology. The list of amino acids in the claims indicates that the invention identified t-PA and discovered all amino acids in t-PA. The t-PA claimed as Inventions A and B is defined as a t-PA obtained through a recombinant DNA technology.

The disclosure of Inventions A and B enabled one skilled in the art to understand the manufacturing method of t-PA with the disclosed characteristics through a recombinant DNA technology. One skilled with his or her general knowledge in the art would have been able to produce a sufficient quantity of t-PA, which was not possible by conventional methods.

As the findings from the expert opinions indicate, if the amino acid sequence of t-PA is identified, t-PA in various forms could be produced. This is also discussed in the specification. These findings support the view that one skilled in the art, with the general knowledge available on the priority date of Inventions A and B, could have readily made t-PA in various forms by replacing a portion of the amino acid sequence recited in the claims, so as to obtain a form of t-PA with improved characteristics. In the Scientists' view, unless a t-PA in a different form reveals characteristics superior to that of the original t-PA, the modified t-PA does not have any practical significance above that of the original t-PA.

Because the 245th position is not in a significant region, the replacement of valine with methionine does not affect the function of the protein, and a t-PA in a different form would have been readily made; it was highly possible or expected on the priority date, for one skilled in the art, to replace valine in the 245th position with methionine in the

t-PA protein so as to obtain a T-PA in a different form with a function comparable to that of the original T-PA. The defendant's witness's statement that the defendant's T-PA resulted from a cloning error also supported that it was well expected for one skilled in the art to obtain a t-PA in a different form resulting from a cloning error.

(The court rejected defendant's arguments that a replacement of valine with methionine would change the characteristics of the protein, relying on the expert opinions that the characteristics of defendant's t-PAs are indistinguishable from those of the patented t-PA.)

III. Negative Element: Prosecution History

1. Prosecution History of Patented Inventions A and B

The original application for Invention A included 16 claims, including a claim which reads: "a DNA human tissue plasminogen activator, having substantially no other human protein." During the examination of the opposition against the application, the JPO examiner upheld the opposition and rejected on the basis of lack of enablement. The examiner agreed with the opponent that the claim was too broad compared with the disclosure. The published claims covered any t-PA having characteristics cited in the claims, which are comparable to the characteristics of natural t-PA. The application, however, did not include any disclosure on variations where amino acid residues in positions 69 through 527 were replaced. Since the characteristics of t-PA in a different form were unknown, the claim scope including these unknown variations was not permitted. In the trial against the decision of refusal, the plaintiff gave up and limited the claims to include a list of amino acids in positions 69 to 527.

Similarly, the original application of Invention B did not include a list of amino acids, and was rejected for lack of enablement, on the ground that the claims were too broad

compared with the disclosure in the specification. To overcome this rejection, the plaintiff introduced the list of amino acids in positions 1 to 527 positions. In its argument accompanying the amendment, the plaintiff emphasized that the introduction of the limitation on the specific sequence of amino acids should not be interpreted to exclude t-PA in different forms, which would be obvious to one skilled in the art from the amino acid sequence cited in the amended claims. This amendment did not satisfy the JPO examiner. The defendant again amended the claim and deleted the words "allelic variations" and "derivatives," these words were pointed out by the examiner as being not fully supported by the disclosure in the application.

Although the claims were amended to recite only the particular amino acid sequence, the specification of Patent Invention A described possible variation resulting from single or multiple amino acid substitutions, deletions, additions or replacements, and made clear that the scope of this invention comprised these variations, as long as they maintained the characteristics of human tissue plasminogen activator. The specification of Patent B also maintained a description that the term "a DNA sequence encoding human tissue plasminogen activator" included all DNA encoding all allelic variations and modifications resulting in derivatives of human tissue plasminogen activator.

These facts in the patent prosecution indicate that the limitation of amino acid sequence was introduced to meet the requirement provided in Article 36, because variations included in the original claims were not supported by the disclosure in the specification. When a claim is amended to overcome the rejection for lack of novelty or inventive step, the invention is not patentable if its scope is interpreted beyond the literal claim scope. Thus, the interpretation is not permissible. In comparison, when a claim is amended to clarify the description of an invention, the interpretation

beyond the literal claim scope would not result in lack of novelty or inventive step and thus should be permissible. Communications from the examiner do not indicate that all variations were excluded from the technical scope of patented t-PA. Thus, no fact in the patent prosecution history gives rise to an element to prevent the court from finding equivalency. No plaintiff's argument gives rise to the application of estoppel.

IV. Argument of Independent Development

A product or method infringes a patent as long as it falls within the technical scope of the patented invention regardless of its independent development from the patented invention. Evidence of the defendant's copying of the patented invention is indirectly relevant to suggest that the interchangeability and obviousness of interchangeability elements are met in affirming equivalency. An argument of independent development is relevant to refute the plaintiff's contention that the accused product meets the two elements of interchangeability and obviousness of the interchangeability, because the defendant copied the patented invention. Because a finding of infringement does not rest on the subjective awareness of the defendant, argument of independent development is not directly relevant to establish nonequivalency by the defendant.

In this case, the plaintiff did not introduce the evidence of the defendant's copying of the patented t-PA. Thus, the defendant's argument was not relevant in determining equivalency.

(Despite the irrelevancy of the evidence on independent development, the court examined evidence on the defendant's process of developing its t-PA and rejected the argument that the defendant independently developed the t-PA.)

V. Conclusion

In summary, no fact which prevents a finding of equivalency was found, and a finding of equivalency between the patented inventions and defendant's t-PA does not upset third parties' reliance on the patent claims. Accordingly, the defendant's t-PA is equivalent to the patented t-PA. The defendant's t-PA, its manufacturing method and thrombolytic agents fall within the technical scope of the patented invention.

It is established that the defendant is preparing to culture the accused cell and manufacture and sell the accused thrombolytic agents by using the accused method. Since these activities constitute infringement of the plaintiff's patents, the plaintiff's request to enjoin the activities, and destroy the accused products, is lawful.

Comments

This case is very important not only because it may completely change case law direction on Japanese claim interpretation, but also because it involves pioneer inventions owned by U.S. biotech company, the significance of the invention is great not only to that company but also to U.S. industry. The Osaka District Court's denial of finding infringement almost resulted in trade disputes between U.S. and Japanese government. Interestingly, infringement suit was also brought against the defendant's licensor in the United States on the basis of the U.S. patents corresponding to Japanese patents in this case (although U.S. patent claims did not include the limitation of amino acid sequence).[1] In appeal from the trial court's finding of infringement, the defendant of the U.S. case did not appeal on the issue of infringement concerning the form of t-PA disputed

[1] *Genentech Inc. v. Welcome Foundation Ltd.*, 29 F3d 1555 (Fed. Cir. 1994).

in Japanese case. Regarding the U.S. defendant's FE1X protein, a different product from the Japanese defendant's product, Federal Circuit found no infringement.

Japanese patent law has been extensively criticized for its narrow claim interpretation and its reluctance to find infringement under the doctrine of equivalents.[2] As typically shown by the first instance decision of this case, when the disputed claim does not literally cover the accused embodiment, Japanese courts find no infringement and reject patentee's request to apply the doctrine of equivalents, giving weight on third parties' interests and legal certainty. When parties dispute a claim term whether the claim includes the accused device, courts find that the claim does not clearly specify the invention, and limits the scope to the scope explicitly or implicitly disclosed in the specification.[3] The recent cases, however, indicate a new tendency in Japanese courts which favors the patentee's interests although even in a most progressive case Tokyo High Court carefully avoided using a term "equivalency or equivalents" as the reason to extend the protection beyond the claim literal scope.[4] The Osaka High Court's determination to change the case law and affirm the doctrine of equivalents is clear from its discussion of patent law policy. In civil law countries,

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[2]For a general discussion of Japanese patent claim interpretation in comparison with United States and German patent claim interpretation, see Takenaka, *Interpreting Patent Claims: The United States, Germany and Japan* (1996).

[3]*Fujitsu v. TI*, Judgment of Tokyo District Court August 31, 1994, reported in Hanrei Jiho (No. 1510) 35 (1995); Hanrei Taimuzu (No. 862) 108 (1995). (In this case, the Tokyo Trial Court rejected the literal coverage of a pioneer invention for manufacturing integrated circuits including the modifications resulting from the later technological development, stating that no suggestion of the modification is found in the disclosure.)

[4]Takenaka, *Case Comment "Ball Spline Bearing"* 26 IIC 683 (1995).

particularly Japan, courts' opinions do not include an extensive discussion on legal theory and policy since their power is limited to solve disputes involved in a particular case. This court opinion begins with an extensive discussion of needs for extending the protection beyond the literal claim scope because the nature of words makes impossible to fully describe an invention, a technical idea, without any ambiguity. The patent policy discussed by the Osaka High Court closely parallels to the United States Patent Policy to make reference to sources other than claims and find infringement under the doctrine of equivalents.[5]

An important rule that the Osaka High Court emphasized was that patent claims must be interpreted as if one skilled in the art would have read the claim. Claims should be read by making reference to the specification, drawings and general knowledge of one skilled in the art. In other words, the protection scope of Japanese patents includes not only disclosed embodiments but also those obvious to one skilled in the art. From now on, expert testimony may take a significant role in Japanese patent infringement cases dealing with high technology such as biotechnology.

A strong U.S. influence is also shown by the test adopted by Osaka High Court. The court's two-part test, examining (1) whether the amino acid recited in the claims is interchangeable with the amino acid in the defendant's t-PA and (2) whether one skilled in the art would have known or conceived the replacement of such amino acids clearly parallels to the interchangeability and known interchangeability tests in determining an insubstantial difference adopted by Federal Circuit in *Hilton Davis Chemical Com-*

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[5]*Autogiro Company of America v. the United States*, 384 F.2d 391 (Ct. Cl. 1967).

pany Inc. v. Warner-Jenkinson Co.[6] Similarly, Osaka High Court's reasoning to reject the defendant's argument of independent development parallels to that of Federal Circuit in *Hilton Davis*, stating that the argument is relevant only if patentee argued that the accused embodiments are copied to establish the interchangeability and known interchangeability between the claimed invention and accused embodiment for finding equivalency. Finally, the Osaka Court followed Federal Circuit in limiting the application of prosecution history estoppelonly when limitations are introduced to overcome a rejection for lack of novelty and inventive step.[7] In short, this t-PA case moved Japanese patent claim interpretation merged with the United States patent claim interpretation. Since *Hilton Davis* has moved United States patent claim interpretation to German counterpart,[8] patent claim interpretation in three major jurisdictions is now in line. Giving the pending disposition before the Supreme Court of *Hilton Davis*, the test and limitation for the doctrine of equivalents the Osaka High Court is premature in the United States at this time. For the sake of harmonization, I cannot help hoping that the Supreme Court would affirm the substantial difference test adopted in *Hilton Davis*.

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[6]*Hilton Davis Chemical Company Inc. v. Warner-Jenkinson Co.*, 62 F.3d 1512, USPQ2d 1641 (Fed. Cir. 1995).

[7]*Id.*, at 1525.

[8]Takenaka, *Doctrine of Equivalents After Hilton Davis: Comparative Law Analysis*, Rutgers Technology and Computer Law Journal (forthcoming 1996 May).